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10/698,031	10/29/2003	Brian Mann	SAVCOR.1C2CP1	1212

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EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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04/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/698,031	Applicant(s) MANN ET AL.	
	Examiner DEBORAH MALAMUD	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-31, 33-100, 119, 121-125 and 146-185 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 165-185 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) See Continuation Sheet is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims rejected are 1-3,7,8,10-18,24-31,37-50,53,57,59-66,68,69,74,75,77-79,82,87-89,91-93,97,100,119,146-151,155 and 157-159.

Continuation of Disposition of Claims: Claims objected to are 4-6,9,13,19-23,33-36,48,51,52,54-56,58,67,70-73,76,80,81,83-86,94-96,98,99,121-123,152-154,156 and 161-164.

DETAILED ACTION

1. The examiner acknowledges the amendments received 11 October 2007. Claims 15, 32, 101-118, 120 and 126-145 are cancelled; new claims 147-185 are added; claims 1-14, 16-31, 33-100, 119, 121-125 and 146-185 are pending.

Specification

2. In view of the amendments to the specification and the abstract received 11 October 2007, the objections to the specification are withdrawn.

Drawings

3. The drawings were received on 11 October 2007. These drawings are accepted.

Claim Rejections - 35 USC § 112

4. In view of the amendments received 11 October 2007, and the cancellation of claims 15 and 32, the rejections under 35 USC 112, second paragraph are withdrawn.

Claim Objections

5. Claim 172 is objected to because of the following informalities: it appears to be an essential duplicate of claim 161. Appropriate correction is required.

Allowable Subject Matter

6. The indicated allowability of claims 12, 28-29, 38-40, 89-90 and 124-125 is withdrawn in view of further consideration of the references. Please see below, "Response to Arguments."

7. Claims 4-6, 9, 13, 19-23, 33-36, 48, 51-52, 54-56, 58, 67, 70-73, 76, 80-81, 83-86, 94-96, 98-99, 121-123, 152-154, 156 and 161-164 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 165-185 are allowed.

Response to Arguments

9. Applicant's arguments filed 11 October 2007 have been fully considered but they are not persuasive. The applicant argues (pages 20-21) that the claims are now allowable that incorporate the subject matter previously indicated allowable. The examiner regrets that upon further consideration of the references, some of the indicated allowable subject matter is withdrawn.

10. With regards to claim 1, which contains subject matter from cancelled claim 32, previously indicated allowable, the examiner considers the pressure transducer/sensor (20) as shown in Figures 1 and 2E of Cohen to be connected to the implantable housing by lead (19). This is an electrical and mechanical connection. Furthermore, just such a connection is indicated in Figure 6 of the Struble reference (sensor 106 and lead 104).

In order to overcome the art of record, the applicant must indicate in the claims how structurally the connection to the housing of the sensor is different from Cohen and Struble.

11. With regards to claim 91, which incorporates subject matter from cancelled claim 101, the examiner does not consider the language “the at least one implantable lead is configured to operate in a plurality of configurations” to be a positively claimed recitation. A lead, such as disclosed by Cohen and Struble (see above) is flexible enough to be guided or steered into a patient’s body. The lead is capable of being bent or twisted into a variety of configurations. Furthermore, it is unclear from the claim language whether the operation of the lead in “a variety of configurations” is meant to entail different electrode configurations, different lead combinations, or different physical positions within the body. The examiner considers the leads as disclosed by Cohen and Struble to satisfy the claimed requirements, since they are capable of being shaped into a variety of positions, and used in a plurality of stimulation strategies.

12. With regards to claim 119, which is amended to include subject matter from cancelled claim 120, the examiner considers the antenna (56; Figure 3) of Struble’s invention to satisfy the requirement “wherein the cardiac rhythm management apparatus and the telemetry apparatus are at least partially contained within an implantable housing.” Figure 3 of Struble is a block diagram illustrating the components of an implantable medical device. The IMD (10) is disclosed as being a pacemaker, which constitutes a cardiac rhythm manager device. These two components are not only each contained within a housing, it is also clear to see that they are contained within the

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same housing, and are functionally cooperative parts of a whole device. In order to overcome the art of record, the applicant must indicate where in the disclosure of Struble is taught a CRM apparatus that is not contained at least partially within an implantable housing with a telemetry apparatus.

13. Regarding claim 146, the applicant argues that the amended subject matter is similar to allowed claim 9. The examiner notes that the phrase "configured to be implanted in the atrial septum of the heart" does not positively claim the applicant's intended invention, as assumed by the examiner. Though Struble and Cohen do not specifically teach implantation within the atrial septum, both sensors are capable of doing so. Furthermore, nothing in the structure of Struble or Cohen's sensor prevents it from being implanted within a subject's atrial septum. The examiner does not consider the amended subject matter to read over the art of record as it pertains to the sensor as claimed. The examiner notes that claim 9 still stands objected to, but allowable over the art of record, suggests amendment of claim 146 to more closely resemble claim 9.

Claim Rejections - 35 USC § 102

14. Claims 1-3, 7-8, 10-11, 14, 16, 24-27, 30-31, 37, 40-41, 43, 44, 53, 57, 59, 61-65, 68-69, 74-75, 77-78, 87-93, 97, 100, 124-125, 146-150, 155 and 157-159 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (U.S. 5,163,429). For a full discussion of the claimed elements, please see above and the previous Non-Final Office Action.

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15. With regards to claims 40, 150 and 155, the examiner does not consider the phrase “configured to be implanted near a shoulder in the medical patient” to be a positive recitation of the applicant's intended invention. The examiner considers the system of Cohen to be capable of being implanted near a shoulder of a patient, and nothing in its structure prevents it from being utilized in this purpose.

16. Regarding claims 89, 100 and 124, the examiner considers the phrase “upgradable” not to limiting beyond a lead that is capable of being removed and/or replaced. The examiner considers the lead of Cohen to be capable of being removed and/or replaced.

17. Regarding claims 90 and 125, the examiner considers Cohen to disclose a lead configured to operate in a plurality of configurations. Please see above, “Response to Arguments.”

18. Regarding claims 147 and 157, the pressure transducer/sensor 20 may alternatively be located in the left Ventricle (Fig.2D), right ventricle (Fig.2A), right atrium (Fig.2B), pulmonary artery (Fig.2H), pulmonary vein, or pulmonary capillary wedge pressure (col.9, lines 50-52).

19. Regarding claims 148 and 158, detected pressure is used to detect hemodynamic compromise. If compromise is detected, the device may generate a cardioversion or defibrillation pulse. See flowcharts of Figs. i 6A, 18A, and 20A.

20. Regarding claims 149 and 159, please see the above discussion, “Response to Arguments,” regarding claim 1.

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21. Claims 1-3, 7, 11, 14, 17-18, 25-26, 30-31, 37, 40, 42-47, 49-50, 53, 57, 59-66, 68, 69, 79, 82, 87-93, 97, 100, 119, 124-125, 146, 149-151, 155 and 159-160 are rejected under 35 U.S.C. 102(e) as being anticipated by Struble (U.S. 6,580,946).

22. With regards to claims 40, 150 and 155, the examiner does not consider the phrase "configured to be implanted near a shoulder in the medical patient" to be a positive recitation of the applicant's intended invention. The examiner considers the system of Struble to be capable of being implanted near a shoulder of a patient, and nothing in its structure prevents it from being utilized in this purpose.

23. Regarding claims 89, 100 and 124, the examiner considers the phrase "upgradable" not to limiting beyond a lead that is capable of being removed and/or replaced. The examiner considers the lead of Struble to be capable of being removed and/or replaced.

24. Regarding claims 90 and 125, the examiner considers Struble to disclose a lead configured to operate in a plurality of configurations. Please see above, "Response to Arguments."

25. Regarding claims 151 and 160, pacemaker 114 contains an antenna 56 (Fig.3) through which it communicates with RF telemetry 130 (Fig.6) and external input/output device 128

26. Regarding claims 149 and 159, please see the above discussion, "Response to Arguments," regarding claim 1.

Claim Rejections - 35 USC § 103

27. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

28. Claims 12, 28-29 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struble (U.S. 6,580,946) or over Cohen (U.S. 5,163,429). Regarding claim 12, Struble and Cohen disclose the claimed invention except for a low compliance titanium foil. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a sensor constructed of a low compliance titanium foil, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

29. Regarding claims 28-29, Struble and Cohen disclose the claimed invention except for a sensor module of a length and diameter of the claimed values and ranges. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a sensor module length of diameter of the claimed values, since it has been held that discovering the optimum value of a result of effective variable involves only routine skill in the art, and since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980); *In re Aller*, 105 USPQ 233.

30. Regarding claim 38, Struble and Cohen disclose the claimed invention but do not disclose expressly the use of a housing having a flat oval shape. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the

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shape of the housing as taught by Cohen and Struble, with the flat, oval-shaped housing, because the applicant has not disclosed the shape of the housing provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the standard IPG shape of housing as taught by Cohen and Struble, because Cohen and Struble's implantable housing contains all of the necessary components to pace the heart of a patient as claimed. Therefore, it would have been an obvious matter of design choice to modify the shape of the housing to obtain the invention as specified in the claim.

31. Regarding claim 39, Cohen and Struble disclose the claimed invention except for a housing of the claimed dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a sensor module length of diameter of the claimed values, since it has been held that discovering the optimum value of a result of effective variable involves only routine skill in the art, and since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233; *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Conclusion

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH MALAMUD whose telephone number is (571)272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Deborah L. Malamud/
Examiner, Art Unit 3766